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Appln. No. 10/701,515
Reply to Office Action dated 1/24/2007

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REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the Official Action dated 24 January 2007. Responsive to that Office Action, Claims 1 and 2 are amended for further prosecution with the other pending claims. With such amendment of claims, there is a further clarification of the pending claims' recitations.

In the Office Action, the Examiner rejected Claims 1-2 and 7-12 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the claims contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed inventions. Specifically, the Examiner pointed out the language "devoid of separate spring members" in Claims 1 and 8 and "only one single lumen" in Claim 9 was unsupported. However, Applicant respectfully submits that such language was inserted pursuant to a telephone interview held with the Examiner on 24 October 2006. The claims discussed were Claims 1, 2 and 4-12. As the Interview Summary indicated, agreement with respect to the claims was reached and in part the Interview Summary stated:

"Applicants discussed potential amendments to the claims that include amending Claim 1 such that it clearly claims a resilient tube

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that has a contractive ability due to its inherent resilience and does not include any additional separate spring member. Applicants also proposed amendments to Claim 9 such that it clearly claims only one single tube, that single tube having an interior lumen containing a balloon member. The Examiner agreed that these changes would overcome the implied references if Applicants can persuasively assert why it would not be obvious to make the separate elements as shown by the reference into integral elements which would result in simplified manufacturing."

As the Examiner had no objections during the interview as for the basis of such limitations, it is rather odd that the Examiner now asserts a 35 U.S.C. §112, first paragraph rejection on those claims to which an agreement was reached. As was discussed during the interview, support is found for such limitations within the specification and figures. With respect to the "devoid of separate spring members", an examination of the figures shows clearly that Applicant's device is one which does not indeed use spring members (to assume an unstressed position). In contradistinction, for example, the Termanini reference clearly shows spring members to be an important element of its device. Applicant, in many instances throughout the specification, refers to the tube as "elastomeric" and "with sufficient stiffness".

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Even beyond this, the reason for the inclusion of such language was based upon the Examiner's suggestions for clarifying the claims and distinguishing such from the Termanini reference. It is telling in this regard that the Examiner now rejects the very language agreed upon during the telephone interview. Although, as stated, Applicant submits that support for such language is found within the Specification and Figures.

With respect to Claim 9 which recites "only one single lumen", Applicant respectfully submits that such does have support in the specification and figures. Looking at Fig. 4 as the Examiner referred to in the Office Action, the longitudinally extending flexible tube clearly shows only one single lumen in which a reversibly inflatable balloon is located. The second lumen, as incorrectly labeled by the Examiner, is clearly the wire control device.

In the Office Action, the Examiner rejected Claims 1-2, 7-8 and 12 under 35 U.S.C. §103(a) as being unpatentable over Spinoza et al. in view of the Termanini reference. In setting forth this rejection, the Examiner acknowledged that the Spinoza reference did not teach that the catheter is sufficiently stiff enough to be inserted into a human without a stylet but cited the Termanini reference for disclosing such concluding that it would have been obvious to one of ordinary skill in the art to make the catheter of Spinoza sufficient stiff.

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As newly-amended independent Claim 1 and previously presented Claim 8 each clearly recite, Applicant's self-retaining urinary drainage catheter system is one which includes among its combination of features a wire control device which is fixably secured at a first end thereof to an inner surface of the closed proximal end of the longitudinally extending flexible tube. Furthermore, Applicant's claimed catheter is inherently resilient, and obviates the need for separate spring members, either plastic or metallic, which are dangerous features in a catheter capable of causing damage to the device and more importantly to a patient.

The full combination of these and other features now more clearly recited by Applicant's pending claims is nowhere disclosed or suggested by the cited Spinoza et al. reference. The Spinoza et al. reference discloses a plurality of strings 28 that extend through the fluid carrying channel within the catheter 10. Each one of the strings is "knotted", with the "knotted end of one of the lengths of the strings 28" passing through aperture 26 and being "retained thereat". Such is clearly shown in Fig. 2 of the Spinoza et al. reference. Whereas, Applicant teaches a wire control device in which a first end is "fixedly secured" to "an inner surface of said of closed proximal end" of the longitudinally extending flexible tube.

As discussed in the interview of 24 October 2006 with the Examiner, the Termanini reference incorporates spring elements that may be helical or a leaf spring where breakage of such springs "could cause severe damage to the bladder

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and urethra". The Termanini reference, knowing and discussing the inherent

dangers and problems of spring elements, still utilizes such in its catheter.

Whereas, Applicant's claimed catheter obviates the need for such spring elements,

a novel concept neither disclosed or suggested by the Termanini reference.

In the office action, the Examiner rejected Claims 9-11 under 35 U.S.C. §103(a) as being unpatentable over the Baskin reference in view of the Rosenberg reference. Referring to Claim 9, Applicant's claimed catheter includes a flexible tube defining only one single lumen. The reversibly inflatable balloon is located "internal said single lumen" and positioned between the plurality of flexible tubes slit portions and connected to an injectable valve situated adjacent to the open distal end of the flexible tube.

The full combination of these and other features clearly recited by Applicant's pending claims is no where disclosed by the cited Baskin and Rosenberg references. As can be readily seen in the figures of the Baskin reference and as stated therein, the inflatable bag "encircles the tubular member rearward of the openings and is secured thereto" (column 1, lines 59-61). The Baskin reference includes a flexible conduit 22 that is connected to a second longitudinal passage 20 to inflate the balloon member which encircles the tubular member. As stated, the Examiner has incorrectly referred to the wire control device as the second lumen. Thus, as the claim clearly recites a "longitudinally

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extending flexible tube" which has "only one single lumen"(language agreed upon by the Examiner), such can not be made obvious by the cited reference. It seems as though the Examiner is disregarding the specification and the figures and applying unfounded meanings to various parts of Applicant's device.

The figures along with the specification clearly show that Applicant does not use spring members in its device. Furthermore, it is clearly seen in the figures that Applicant's flexible tube includes only one single lumen. Thus, the Spinoza, et al., Termanini, Baskin and Rosenberg references, even when considered together, fail to disclose or suggest the unique combination of elements now clearly recited by Applicant's pending claims for the purposes and objective disclosed in the subject patent application.

It is now believed that the subject patent application has been placed in condition for allowance and such action is respectfully requested.